# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference | **FOR FURTHER ACTION** | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
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| G06T17/00 | | |
| Applicant | | |
| CONSIGLIO NAZIONALE DELLE RICERCHE et al. | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 12 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

| Date of submission of the demand | Date of completion of this report |
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| 31.03.2004 | 28.02.2005 |
| Name and mailing address of the international preliminary examining authority: | Authorized Officer |
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# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IT 03/00564

## I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

**Description, Pages**

| | |
|---|---|
| 1, 4-16 | as originally filed |
| 2, 3, 3a | received on 31.12.2004 with letter of 31.12.2004 |

**Claims, Numbers**

| | |
|---|---|
| 2-24 | as originally filed |
| 1 | received on 31.12.2004 with letter of 31.12.2004 |

**Drawings, Sheets**

| | |
|---|---|
| 1/8-8/8 | as originally filed |

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   *(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | 2-5,9-11,14-15,22-24 |
| | No: | Claims | 1,6-8,12-13,16-21 |
| Inventive step (IS) | Yes: | Claims | |
| | No: | Claims | 1-24 |
| Industrial applicability (IA) | Yes: | Claims | 1-24 |
| | No: | Claims | |

2. Citations and explanations

**see separate sheet**

## VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Reference is made to the following documents (D6 and D7 have not been cited in the search report):

D1: XP008031529, "Fabrication of dynamic optical head phantoms from an MRI head model", Yukari Tanikawa-Takahashi, and Yukio Yamada, 1998

D2: XP4127714, "Segmentation of 2D and 3D images through a hierarchical clustering based on region modelling", Xinquan Shen, Michaek Spann, Peter Nacken, 1998

D3: "http://www.tele.ucl.ac.be/PEOPLE/OC/these/node100.html", Olivier Cuisenaire, 10.05.1999

D4: XP10101571, "A novel method for 3-D segmentation and volume estimation of brain compartments from MRI", Jacob M. Agris, Rui deFiguelredo, 1991

D5: XP008031530, "Design and fabrication of a solid simplified head phantom", Yukari Taikawa-Takahashi, Daigo Imai, Sho Mizuno, Hiroshi Maki, 1997

D6: "A PVA-C brain phantom derived from a high quality 3D MR data set", Kathleen JM Surry, Terry M Peters, Proceedings of the Fourth International Conference on Medical Image Computing and Computer-Assisted Intervention (MICCAI), Utrecht, the Netherlands, October 14 – 17, 2001, XP001091508

D7: "Rapid Prototyping with Stereolithography", Joseph De Falco, Spring 1997 http://users.bergen.org/jdefalco/SLA5.html , XP001091509

2. NOVELTY:
The subject-matter of claims 1, 6-8, 12-13, 16-21 is not novel in the sense of Article 33(2) PCT.

2.1. Document 1 (D1) discloses the subject matter of claim 1:

- a process for preparing a three-dimensional digital image for realising a biomorphic multicompartmental phantom (D1, page 513, the first paragraph, the second sentence;

page 513, the third paragraph, the second sentence; page 513, the fourth paragraph, the first sentence; page 515, last sentence - page 515, the first sentence ), representing at least one organ and/or at least one system belonging to a living being (D1,page 513, the fourth paragraph, the first sentence), comprising a first phase A.1 of acquisition of images or "sequences" of the organ or of the system belonging to the living being, according to predefined acquisition parameters (D1, page 513, the first paragraph, the last sentence), forming a volumetric image defined by voxels (D1, page 515, the sentence "Then five prototypes..", the term "3-D shape of five tissue types" implicitly discloses a volumetric image by voxels ), further comprising a phase A.2 of identification of tissues and/or tissue liquids and a phase B of selection of at least three of said tissues and/or tissue liquids ( D1, page 514, the first sentence; page 516, table 1), the process being characterised in that it comprises the following phases:

C.1 verifying the adjacency of the voxels, so that each tissue or tissue liquid defines a connected volume representing the tissue or tissue liquid itself (D1, page 514, the first sentence-page 515, the first paragraph; the determination of the "outer 3-D shapes of five tissue types" implicitly discloses the verification of the adjacency of the voxels);

C.3 preparing an image presenting the surfaces of the tissue volumes defined according to the following sub-phases:

C.3.2 determining a number of surfaces equal to the number of tissues, such that they result internal to one another, even if partially tangent, said surfaces being the convolution of the surfaces of one or more volumes representing the tissue or tissue liquid itself, said surfaces giving, by addition or subtraction, all the surfaces corresponding to the tissues or tissue liquids selected in phase B ( D1, page 514, the first sentence - page 515, the sentence starting with "All prototypes..") ;

C.3.3 assigning a thickness to said surfaces, so that in the portions wherein two or more surfaces are tangent to one another the thickness is assigned to only one surface, the set of said thicknesses forming a connected volume ( D1, page 513, third paragraph, the sentence starting with "After finishing the first layer..", figure 6-7).

Therefore, the subject matter of claim 1 is not new.

Furthoremore, it should be noted that rapid prototyping(stereolithography)of 3d shape images to produce complex solid models is well known in the prior art since 1987 (see further D7). The brain phantom fabrication automatization is also within the

implementation subjects of this technique as exemplified in D6 (abstract, the first sentence; the section "Introduction", last sentence; the section "4 Conclusions").

A similar objection applies to the subject matter of apparatus, computer program, memory medium claims 17,18,19.

2.2. Document 1 (D1) discloses the subject matter of claim 6:

Process according to any one of the claims 1 to 5, characterised in that it carries out, before phase C.3.2, the following phase:

C.3.1 transforming the vector representation of the voxels into the vector representation of the surfaces separating the several tissues ( D1, page 514, the first sentence - page 515, the sentence starting with "All prototypes.." ; the outer 3-D shapes of five tissue types are the surface representations of the tissues).

Therefore, claim 6 is not new.

2.3. Document 1 (D1) discloses the subject matter of claim 7:

Process according to any one of the claims 1 to 6, characterised in that the organ of the living being, the images of which are acquired in phase A.1, is the brain of a superior primate ( D1, page 513, the fourth paragraph, the first sentence starting with "The stack..").

Therefore, claim 7 is not new.

2.4. Document 1 (D1) discloses the subject matter of claim 8:

Process according to claim 7, characterised in that the organ of the living being, the images of which are acquired in phase A.1, is the brain of a human being (D1, page 513, the fourth paragraph, the first sentence starting with "The stack..").

Therefore, claim 8 is not new.

2.5. Document 1 (D1) discloses the subject matter of claim 12:

Process according to any one of the claims 7 to 11, characterised in that said at least

three tissues or tissue liquids selected in phase B are the grey matter, the white matter and the encephalorachidian liquid ( D1, page 513, the second sentence starting with "The optical..").

Therefore, claim 12 is not new.

2.6. Document 1 (D1) discloses the subject matter of claim 13:

Process according to any one of the claims 7 to 12, characterised in that during phase C.3.2 a first surface containing the white matter plus the grey matter, a second surface containing only the grey matter, and a third surface representing the cranium surface are selected, the volume containing the encephalorachidian liquid and the volume containing only the white matter being obtained by subtraction between said surfaces ( D1, figures 6.3, 6.6, 6.7 and section 3 in general ).

Therefore, claim 13 is not new.

2.7. Document 1 (D1) discloses the subject matter of claim 16:

Process according to any one of the previous claims, characterised in that the image obtained from phase C.3.3 is modified so as to create channels entering the compartments/chambers corresponding to the selected tissues or tissue liquids, said channels being used for filling and emptying the phantom (D1, figure 6-7; page 519, the paragraph starting with the sentence "Other layers..").

Therefore, claim 16 is not new.

2.8. Document 1 (D1) discloses the subject matter of claim 20:

Biomorphic multicompartmental phantom, suitable for multianalytical examinations, characterised in that it is produced through a rapid prototyping device using the images processed according to the process according to any one of the claims 1 to 16 (see the argumentation for claim 1), the surfaces having thickness being made of solid synthetic matter ( D1, page 516, the first sentence and the section "2.4 Casting") and the volumes representing the various tissues and/or tissue liquids being left empty and so forming several fillable compartments ( D1, page 517, the first paragraph).

Therefore, claim 20 is not new.

2.9. Document 1 (D1) discloses the subject matter of claim 21:

Phantom according to claim 20, characterised in that the rapid prototyping device is a stereolithographer ( D1, page 513, the first paragraph, the sentence starting with "Shapes..").

Therefore, claim 21 is not new.

3. INVENTIVE STEP:

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 2-5, 9-11, 14-15, 22-24 does not involve an inventive step in the sense of Article 33(3) PCT.

3.1. The document **D1** is regarded as being the closest prior art to the subject-matter of claim 1 as cited above, see the paragraph "2. NOVELTY".

The subject-matter of claim 2 differs from this known D1 in that the method for verifying the adjacency of the voxels (connected component algorithm in voxel space; claim 2 characterising the step C.1 in claim 1) is not explicitly explained in D1 although a kind of adjacency between classified pixels in the slices must exist to create the outer 3-D shape of five tissue types for the prototyping machine.

The problem to be solved by the present invention may therefore be regarded as a method for the verification of the adjacency of the voxels to derive the connected volumes of human brain compartments.

The solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons.

The process of automatic fabrication of a multicompartmental realistic brain phantom, using MRI images as input, is disclosed in D1 as discussed above.

To determine the 3-D brain volumes in this process, connected component analysis has been proposed in the application. However, connected component analysis is a well known technique in the prior art of this field. D2 and D3 exemplify this method both in 2-D and 3-D domains of brain images (see further the citation regarding claim 2 below). Furthermore, the input (image sequences) and output (segmented tissue surfaces) are

the same for both documents as in the application, which also shows the interchangeability of connected volume derivation methods for the whole brain phantom fabrication process.

Therefore, the skilled person in the art would implement the connected component clustering algorithm of D2 in the process of automatic fabrication of a multicompartmental realistic brain phantom as disclosed in D1. Claim 2 does not involve an inventive step.

Regarding claim 2:

Document 2 (D2) discloses the subject matter of claim 2:

a process according to claim 1, characterised in that phase C.1 , verifying the adjacency of the voxels, so that each tissue or tissue liquid defines a connected volume representing the tissue or tissue liquid itself ( D2, page 1300, the section "3.2.4. Clustering algorithm"; page 1304, left hand column, lines 11-17), comprises the following sub-phases:

C.1.1 selecting a voxel from the set of voxels forming the whole acquired volume ( D2, page 1298, left hand column, the formula (8),V0);

C.1.2 comparing the selected voxel with a neighbourhood of six voxels which are connected to it through one face ( D2, page 1298, left hand column, the formula (8), in which p=6; the comparison of voxels, i.e. dissimilarity and predicate functions in D2 are explained in general the sections 3.2.1, 3.2.2, 3.2.3) ;

C.1.3 if another voxel of the same type (belonging to the same tissue or tissue liquid) does exist in said neighbourhood, examining the neighbourhood of this one, and so on recursively ( D2, page 1298, right hand column, the section "A. At the base level"; page 1300, left hand column, section 3.2.4) .

C.1.4 if during phase C.1.3 an island of one or more connected voxels of the type selected in phase C.1.1 is defined, which is surrounded by one or more volumes of voxels of other types, carrying out the following sub-phase:

C.1.4.1 if said island has size smaller than a predetermined threshold, assigning the voxels of said island to the tissue which is most represented in a region including the

island (D2, page 1300, right hand column, lines 6-9).

3.2. Regarding claim 3:

Document 2 (D2) discloses the subject matter of claim 3:

Process according to claim 1 or 2, characterised in that it further comprises, after phase C.1.4.1, a phase C.1.4.2 wherein, according to the method of the previous phases, the existence of islands having size larger than said threshold is verified and, in the positive ( D2, page 1304, right column, lines 11-23 introduces this merging case, i.e. if a homogenous region is a part of an object region but not larger than a noisy area in size), one of the following sub-phases is alternatively carried out:

- reassign the island to one of said tissues or tissue liquids ( the algorithm to merge two regions is disclosed in D2, the section 3.2.2, the paragraph starting with "At non-base levels" and section "B. At non-base levels").

- connecting the island, through a channel, to one of said tissues or tissue liquids (it is obvious that manual clustering is always possible).

Therefore, claim 3 does not involve an inventive step.

3.3. Regarding claim 4:

It is well known to the person skilled in the art that lossy smoothing can be applied in any image processing algorithm for the purpose of more homogeneous data.

Therefore, claim 4 does not involve an inventive step.

3.4. Regarding claim 5:

Document 2 (D2) discloses the subject matter of claim 5:

Process according to any one of the claims 1 to 4, characterised in that phase B further comprises the following phases:

B.1 eliminating all the tissues except a predetermined set of tissues ( D2, page 1304, left hand column, lines 14-17 discloses the predetermined set of tissues that the

algorithm in D2 clusters);

B.2 filling the holes by assigning the corresponding voxels to at least one tissue of the predetermined set ( D2, page 1300, right hand column, "Here, a region..").

Therefore, claim 5 does not involve an inventive step.

3.5. Regarding claim 9:

D1 discloses "249" as the number of axial images, "0.2mm" as the layer thickness and "0.8mm" as the centre to another spacing ( D1, page 513, last paragraph, the sentences "the original.." and "Therefore,..").

The parameters in claim 9 are only similar design parameters and for the person skilled in the art, it is obvious to implement similar parameters.

Therefore, claim 9 does not involve an inventive step.

3.6. Regarding claim 10:

Document 1 (D1) discloses the subject matter of claim 10:

Process according to claim 9, characterised in that said images which are acquired are MRI images ( D1, page 513, the third paragraph, the second sentence starting with "Rapid prototyping can fabricate..").

Therefore, claim 10 does not involve an inventive step.

3.7. Regarding claim 11:

The parameters T1, T2, PD are well known in the prior art and used to produce T1-, T2- and PD-weighted MR images to identify different tissues (For more details, D3). It is obvious that the T1-w and PD-T2-w sequences would be acquired by the skilled person in such a study.

Therefore, claim 11 does not involve an inventive step.

3.8. Regarding claims 14,15:

It is obvious that the correction of tissue definition by human operators is always possible after an automatic image process.

Therefore, claim 14,15 does not involve an inventive step.

3.9. Regarding claims 22,23,24:

According to D1, said compartments of the phantom are filled with a liquid, the optical properties, i.e. the scattering and absorption coefficients, of which are changed to simulate the temporal change of the physiological states (page 517, the first paragraph, the second, third and forth sentences) .

It is obvious that various mixtures of liquids can be used in various optical tomography devices using the same phantom prototype.

The material-device combinations mentioned in claims 22,23,24 are well known in the prior art.

Therefore, claims 22,23,24 do not involve any inventive step.

4. INDUSTRIAL APPLICABILITY:

The current set of claims 1-24 discloses technical features to implement an image processing method of automated head phantom prototyping and therefore, the subject matter of claims 1-24 are industrial applicable.

5. NOTES:

5.1. The independent claim 1 discloses the term "convolution" in wording. This term has a very specific meaning in Digital Signal Processing. But, as far as understood, such a transformation is not intended in claim 1. Therefore, the wording of claim 1 should be reformulated.

5.2. As far as understood from the description (the description, page 10, lines 13-15), the subject matter of claims 14-15 relates only to the further manual corrections by an human operator. However, the current wording is more general and does not give the intended meaning.

To the knowledge of the inventors, the phantoms of anthropomorphic type realised so far are:

- the 2D or 3D brain phantom by Hoffman for use in nuclear medicine;
- an anthropomorphic phantom of torso for use in nuclear medicine;
- CIRS 3D brain phantom for localization for use in operations;
- Striatal Phantom for use in PET/SPECT by Alderson;
- CROBOT of torso for use in colonoscopy; and
- NEUROBOT, a brain phantom for localization for operations;
- the phantom realised by Tanikawa et al. for optical tomography

The phantom by Hoffman is a series of plastic discs which form a fillable chamber simulating the brain wherein the grey matter is completely filled with the solution containing the tracer, while the solid layers, reducing the volume which may be occupied by the solution, which simulate the behaviour of the white matter in nuclear medicine (with a ratio of 4:1 between the tracer concentration for the grey matter and the one for the white matter). The phantom does not itself represent a human brain, but it simulates its behaviour so that the images of nuclear medicine seem the ones of a real brain, instead the images of Magnetic Resonance or of CT do not appear so.

The CIRS 3D brain phantom is a cast of the scalp realised in a material which may be displayed on radiographic, CT and MRI images. The phantom simulates the bone of the cranium and the flesh surrounding it and it may be used for localization problems during surgical operations. The phantom is not multicompartmental, it cannot be used in nuclear medicine (MN) and its use is strictly limited to the application for which it has been realised.

The Striatal Phantom is anthropomorphic and multicompartmental, but the represented compartments are made of the caudate nuclei, the putamen and the rest of the brain, with no separation among white matter, grey matter and cerebrospinal fluid. It may be used in MN, CT and MRI but only for imaging the striatum.

The CROBOT phantom, still under prototyping, provides for the construction of a hollow human torso internally having a structure similar to the colon in order to be capable to simulate operations in colonoscopy, while the NEUROBOT phantom should represent a brain for leading a surgeon during certain operations.

The phantom realised by Tanikawa et al. for optical tomography provides a phantom with internal free spaces through which liquid can flow to simulate dynamically some brain functions.

Each one of the phantoms listed above is intended for a well specific application, that is for setting machines for a limited set of analytical methods often applied only to specific organs or tissues.

This limitation has enabled, from time to time, the avoidance of technical and practical problems, by selecting the most favourable technique of realisation to a specific case.

Consequently, no one of the single aforesaid phantoms may be suitable for setting all the PET, SPECT, MRI, MN, CT, CAT techniques or methods, simulating any type of tissue or even any set of tissues, and leading to an anthropomorphic representation of the concerned organs or tissues.

If any phantom among the ones listed above is taken, and it is used in another application, it does not work or it gives only approximate results not suitable for testing the analysing machines.

Even the phantom realised by Tanikawa et al. for optical tomography has severe limits, in that the internal free spaces have to be fabricated by hands: it cannot be realistic and its fabrication is cumbersome.

The aforesaid limitations actually come from the lack of an automated process which enables to pass from images of living beings to the effective production of the phantom and which comprises a processing which minimises the information of said images in order to save the production resources and hence to minimise the product cost, keeping in any case the universality of the produced phantom.

It is therefore an object of the present invention an automated process for generating three-dimensional maps of a multicompartmental and anthropomorphic phantom for use in researches which are conducted with different procedures, even multiple ones, by simulating any group of organic tissues.

It is still a specific object of the present invention a phantom which is produced starting from the maps which are obtained through the process according to the present invention.

It is therefore subject matter of this invention a process for preparing a three-dimensional digital image for realising a biomorphic

multicompartmental phantom, representing at least one organ and/or at least one system belonging to a living being, comprising a first phase A.1 of acquisition of images or "sequences" of the organ or of the system belonging to the living being, according to predefined acquisition parameters, forming a volumetric image defined by voxels, further comprising a phase A.2 of identification of tissues and/or tissue liquids and a phase B of selection of

CLAIMS

1. Process for preparing a three-dimensional digital image for realising a biomorphic multicompartmental phantom, representing at least one organ and/or at least one system belonging to a living being, comprising a first phase A.1 of acquisition of images or "sequences" of the organ or of the system belonging to the living being, according to predefined acquisition parameters, forming a volumetric image defined by voxels, further comprising a phase A.2 of identification of tissues and/or tissue liquids and a phase B of selection of at least three of said tissues and/or tissue liquids, the process being characterised in that it comprises the following phases:

C.1 verifying the adjacency of the voxels, so that each tissue or tissue liquid defines a connected volume representing the tissue or tissue liquid itself;

C.3 preparing an image presenting the surfaces of the volumes defined in phase C.1 according to the following sub-phases:

C.3.2 determining a number of surfaces equal to the number of tissues, such that they result internal to one another, even if partially tangent; said surfaces being the convolution of the surfaces of one or more volumes defined in phase C.1, said surfaces giving, by addition or subtraction, all the surfaces corresponding to the tissues or tissue liquids selected in phase B;

C.3.3 assigning a thickness to said surfaces, so that in the portions wherein two or more surfaces are tangent to one another the thickness is assigned to only one surface, the set of said thicknesses forming a connected volume.

2. Process according to claim 1, characterised in that phase C.1 comprises the following sub-phases:

C.1.1 selecting a voxel from the set of voxels forming the whole acquired volume;

C.1.2 comparing the selected voxel with a neighbourhood of six voxels which are connected to it through one face;

C.1.3 if another voxel of the same type (belonging to the same tissue or tissue liquid) does exist in said neighbourhood, examining the neighbourhood of this one, and so on recursively;

C.1.4 if during phase C.1.3 an island of one or more connected voxels of the type selected in phase C.1.1 is identified, which is